HF1-35 d1572b

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124025

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-3591

April 14, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Susan Bielanski, Office Manager
MPPI Physicians
341 North Calvert Street, Suite 300
Baltimore, Maryland 21202

Inspection ID #1108660009

Dear Ms. Bielanski:

Your facility was inspected on March 27, 1998 by a representative of the State of Maryland's Radiological Health Program acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving mammography operations performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding:

> **The number of masses scored in the phantom image was 1.5 and did not meet the required number. The minimum number required for masses is** [redacted]
> The inspector scored two phantom images that were taken using your mammography X-ray machine, a [redacted]. Both images failed to meet the minimum number of [redacted] visible masses with clear round borders. Scoring was stopped after the second mass was read, as it did not have a clear round border.

The specific problem noted above appeared on your MQSA Facility Inspection Report, issued at the close of the inspection. This problem is identified as Level 1 since it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could

compromise the quality of mammography performed at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 repeat noncompliance that was listed on the inspection report provided to you at the close of the inspection, specifically:

> **The following interpreting physicians did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3-year period:** [redacted]

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Equipment settings (include technique factors), raw test data, and calculated final results, where appropriate; and
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

Please submit your response to the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, Attn: Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at (804) 379-1627, extension 14. Also, send a copy to the State radiation control office that conducted the referenced inspection.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to inspectional findings and does not necessarily address other obligations you may have under the law. You may obtain general information concerning all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have specific questions concerning mammography facility requirements or the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely yours,

William M. Ment

William M. Ment
Acting Baltimore District Director